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S/N 10/551,898 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Moriwaki et al.	Examiner:	Larry R. Wilson
Serial No.:	10/551,898	Group Art Unit:	3767
Filed:	January 5, 2006	Docket No.:	10873.1788USWO
Title:	MEDICAL NEEDLE DEVICE WITH WINGED SHIELD		

CERTIFICATE OF TRANSMISSION
I hereby certify that the papers listed below are being transmitted by EFS Web to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 23, 2010.

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APPELLANT'S REPLY BRIEF

Dear Sir:

This Reply Brief is presented in response to the Examiner's Answer mailed May 24, 2010 and stems from the final rejection of claims 1 and 4-7 in the above-identified application, as set forth in the final Office Action mailed November 23, 2009.

Page 7 of the Answer disputes Appellants' argument that because the flexible delivery tube and flexible duct of Whisson (US Patent No. 5,762,632) would not adequately transfer force to cause insertion of the needle, the intended purpose of Teraoka (EP 1 048 311) is rendered inoperable. Appellants continue to disagree. A primary purpose of the winged injection needle device in Teraoka is to convey a liquid solution into a patient's body (see Teraoka, col. 7, lines 10-13), and as a result, an axial insertion force has to be transmitted to the tip of the needle 2 to insert the needle into the patient's body. As clearly show in, e.g., Fig. 1, during the insertion, the Teraoka needle device allows the user to use one hand to hold onto wings 7 to administer the lateral movement of the needle 2 and allows another hand to hold onto a front end of the tube 4 to apply an axial insertion force. The Teraoka needle device 1 is not configured to enable the tip of the needle 2 to insert into the patient's body merely by applying a force to the wings 7 because

the needle 2 is slidable relative to the protector 8 where the wings 7 are attached (see Teraoka, col. 5, lines 28-29). Therefore, Appellants respectfully contend that if the Teraoka holder 3 is modified by the flexible delivery tube 13, which may be made of flexible resilient material (see Whisson, col. 1, lines 16-19), the axial insertion force would not be adequately transferred to the tip of the needle 2 to cause the needle to insert into the patent's body. As a result, Teraoka is rendered inoperable for one of its primary purposes, which is to convey a liquid solution into a patient's body.

Page 7 of the Answer contends that "the wings [7] are used to stabilize and push the needle into the patient's skin." Appellants respectfully contend that the Teraoka needle device 1 is not configured to enable the tip of the needle 2 to insert into the patient's body merely by applying a force to the wings 7. Teraoka discusses the following:

> "It is preferable that the diameter of the pore 11 of the protector tip 10 is 1.1 to 2.0 times the diameter of the injection needle 2. It is sufficient that the cavity of the protector tip 10 has a diameter such that the injection needle 2 can smoothly penetrate through the cavity; when the diameter is too large, the needle tip cannot be well maintained at the time of sticking. On the contrary, when the diameter is too small, it is difficult for the injection needle to freely slide when the injection needle is covered and contained." (Emphasis added)

Teraoka, col. 6, line 56 to col. 7, line 7. As acknowledged in the first two lines of the Answer on page 8, the diameter of the pore 11 in Teraoka is "small enough to prevent excessive lateral movement during penetration." The smallness of the pore 11 is not used for pushing the needle into the patient's skin as suggested in the Answer, but for preventing excessive lateral movement during penetration. As clearly shown in, e.g., Fig. 1, the Teraoka protector 8 including the wings 7 is axially movable relative to the needle 2. The only force that restrains the axial movement between the protector 8 (including the wings 7) and the needle 2 is caused by the stretchable member 6. But apparently, the stretchable member 6 is not used to transfer an axial insertion force from wings 7 to a rear end of the needle 2 to pull the needle 2 to insert into the patient's body, because this merely would stretch the stretchable member 6, instead of transferring an axial force to the needle 2. Therefore, it is incorrect to say that the wings are used to push the needle into the patient's skin.

Page 8 of the Answer contends that "the [Whisson] flexible delivery duct [when used to modify the Teraoka protector 8] allows the bending when the needle is extended and latched in the penetrating position." Appellants respectfully contend that it is improper to use the Whisson flexible duct 23 to modify the Teraoka protector 8. As clearly stated at col. 2, lines 5-6 of Teraoka, the object of the Teraoka invention is "to provide a winged injection needle device satisfying . . . three conditions," including "to contain a used injection needle safely and easily (see Teraoka, col. 2, lines 2-4)." To realize this object, Teraoka further states that:

> "[I]t is rather desirable that the protector 8 and the wing 7 are made of different members in terms of the application or function. It is because the wing 7 generally requires a flexibility so as to easily follow the skin, while the protector 8 requires the hardness so as to hold and contain the injection needle 2" (Emphasis added)

Teraoka, col. 6, lines 45-51. However, the Whisson flexible duct 23 is made of flexible material, e.g., closely wound core coil (see Whisson, col. 3, line 18). The Whisson flexible duct 23 may be safe when containing the flexible delivery tube 13 in Whisson, but clearly would cause risks when used as a protector to protect a needle in Teraoka. For example, because of the flexibility, it would be difficult for the modified protector to maintain its shape upon application of an outside force. As a result, the tip of the needle is likely to pierce the wall of the protector and cause needle stick injuries. This would destroy an intended purpose of Teraoka, which is to contain a injection needle safely and easily. Therefore, it is improper to use Whisson flexible duct 23 to modify the Teraoka protector 8.

Page 9 of the Answer contends that "since [Whisson] flexible tubes can kink in extreme bends, Whisson would suggest using the flexible delivery tube and shield to render the infusion set [in Teraoka] unsuitable for later use, which would satisfy the purpose of Whisson and Teraoka of providing a safe and easily contained injection needle to prevent needle stick injuries." Appellants respectfully contend that one skilled in the art would not be motivated to modify Teraoka for this reason. Whisson states that:

> "[T]he movement of the engaging means [27] to the retracted position may cause a destructive bending or 'kinking' of the delivery tube to render the infusion set incapable of further use. In the case of the embodiment described above in relation to the drawings the arrangement of the slider [27] with respect

> to the base [11] is such that in the event of inadvertent movement of the slider [27] from the retracted position to the extended position the delivery tube [13] folds up or 'kinks' rather than causing movement of the needle [12] to the extended position."

Whisson, col. 4, line 61 to col. 5, line 3. Clearly, this paragraph merely discusses that the engagement means or slider 27 in a housing 13 can be configured to cause a destructive bending or kinking of the delivery tube to prevent the needle 12 from extending to the extended position (see Whisson, Figs. 1-3). Indeed, without the slider 27, the flexibility of Whisson delivery tube 13 or duct 23 would not by itself cause the tube or duct to bend or kink. Therefore, this would not motivate one skilled in the art to use the flexible tube 13 and duct 23 of Whisson to modify the holder 3 and protector 8 of Teraoka, respectively.

Dependent claims 4-7 are considered to stand or fall together with independent claim 1 for the purposes of this appeal only. Appellants are not conceding the correctness of the discussion of the issues for claims 4-7 at pages 5-6 of the Answer.

Appellants submit that the rejection is untenable for the reasons set forth above and should be reversed. Please charge any additional fees or credit any overpayment to Deposit Account No. 50-3478.

Respectfully submitted,

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Date: July 23, 2010

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